

# GENERAL VITAMIN CORP

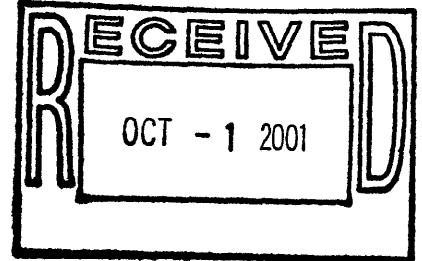
PO Box 1500 Chapel Hill NC 27516

919-929-5785 fax 919-929-2458

September 27, 2001

## CERTIFIED MAIL

Return Receipt Requested



Office of Nutritional Products, Labeling and Dietary Supplements  
HFS-800  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street, SW  
Washington, D.C. 20204

To Whom it May Concern,

This notification is submitted pursuant to Section 403 (r)(6) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 343(r)(6), for the purpose of notifying the agency of statements being made in the labeling of a dietary supplement distributed by this company.

The product name and the dietary ingredients for which the statements are being made are as follows:

### **Horny Goat Weed**

Horny Goat Weed	500mg
(Epimedium sagittatum, Epimedium brevicornum) Standardized 10% Icariin	
Maca Pure (Lepidium meyenii)	250mg
Standardized to contain 0.6% macamides And macaenes	
Mucuna pruriens	33.3mg
Standardized 15% L-Dopa (L-Dihydroxy- Phenylalanine)	
Polypodium vulgare	25mg
Standardized 8% 20-EDC (20-Hydroxyecdysone)	

97S 0162

LET 8632

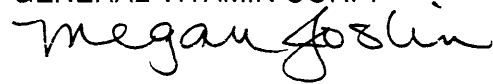
The text of the statements that are being made in regards to the above stated product are listed below:

-known as a natural herbal sexual enhancer that may help performance, desire and increase satisfaction

I certify that the information contained in this notice is complete and accurate, and that General Vitamin Corporation has substantiation that the statements are truthful and not misleading.

Sincerely,

GENERAL VITAMIN CORP.

A handwritten signature in black ink that reads "Megan Joslin". The signature is written in a cursive, flowing style.

Megan Joslin  
Product Development Coordinator